

SECOND REGULAR SESSION
[PERFECTED WITH PERFECTING AMENDMENT]
HOUSE COMMITTEE SUBSTITUTE FOR
HOUSE BILL NO. 1332
94TH GENERAL ASSEMBLY

Reported from the Special Committee on Healthcare Transformation February 14, 2008 with recommendation that House Committee Substitute for House Bill No. 1332 Do Pass. Referred to the Committee on Rules pursuant to Rule 25(21)(f).

Reported from the Committee on Rules February 28, 2008 with recommendation that House Committee Substitute for House Bill No. 1332 Do Pass, with no time limit for debate on Perfection.

Taken up for Perfection April 9, 2008. House Committee Substitute for House Bill No. 1332 ordered Perfected and printed, as amended.

D. ADAM CRUMBLISS, Chief Clerk

3027L.05P

AN ACT

To amend chapter 338, RSMo, by adding thereto four new sections relating to pharmacists and pharmacies, with a penalty clause for certain sections.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Chapter 338, RSMo, is amended by adding thereto four new sections, to be
2 known as sections 338.600, 1, 2, and 3, to read as follows:

338.600. 1. Notwithstanding any other provision of law to the contrary, when an
2 **audit of the records of a pharmacy licensed in this state is conducted by a managed care**
3 **company, insurance company, third-party payor, the department of insurance, financial**
4 **institutions and professional registration, or any entity that represents such companies,**
5 **groups, or department, such audit shall be conducted in accordance with the following:**

6 **(1) The entity conducting the initial on-site audit shall provide the pharmacy with**
7 **notice at least one week prior to conducting the initial on-site audit for each audit cycle;**

8 **(2) Any audit which involves clinical judgment shall be conducted by or in**
9 **consultation with a licensed pharmacist;**

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

10 (3) Any clerical or recordkeeping error, such as a typographical error, scriveners
11 error, or computer error, regarding a required document or record shall not in and of
12 itself constitute fraud or grounds for recoupment; except that, such claims may be
13 otherwise subject to recoupment or payment of any discovered underpayment. No such
14 claim shall be subject to criminal penalties without proof of intent to commit fraud;

15 (4) A pharmacy may use the records of a hospital, physician, or other authorized
16 practitioner of the healing arts involving drugs or medicinal supplies written or
17 transmitted by any means of communication for purposes of validating the pharmacy
18 record with respect to orders or refills of a legend or narcotic drug. Electronically stored
19 images of prescriptions, electronically created annotations and other related supporting
20 documentation shall be considered valid prescription records. Hard copy and electronic
21 signature logs that indicate the delivery of pharmacy services shall be considered valid
22 proof of receipt of such services by a program enrollee;

23 (5) A finding of an overpayment or underpayment may be a projection based on
24 the number of patients served and having a similar diagnosis or on the number of similar
25 orders or refills for similar drugs; except that, recoupment of claims shall be based on the
26 actual overpayment or underpayment unless the projection for overpayment or
27 underpayment is part of a settlement as agreed to by the pharmacy;

28 (6) Retail, hospital, and mail order pharmacies shall be audited under the same
29 standards and parameters as other pharmacies of the same class audited by the entity;

30 (7) A pharmacy shall be allowed at least thirty days following receipt of the
31 preliminary audit report in which to produce documentation to address any discrepancy
32 found during an audit;

33 (8) The period covered by the audit shall not exceed a two-year period beginning
34 two years prior to the initial date of the on-site portion of the audit. The audit shall only
35 review claims that, during the same audit period, were submitted to or adjudicated by the
36 managed care company, insurance company, third-party payor, the state of Missouri, or
37 any entity that represents such company or group conducting the audit;

38 (9) An audit shall not be initiated or scheduled during the first five business days
39 of any month due to the high volume of prescriptions filled during such time unless
40 otherwise consented to by the pharmacy;

41 (10) The preliminary audit report shall be delivered to the pharmacy within one
42 hundred twenty days after conclusion of the audit, with reasonable extensions permitted.
43 A final audit report shall be delivered to the pharmacy within six months of receipt by the
44 pharmacy of the preliminary audit report or final appeal, as provided for in subsection 3
45 of this section, whichever is later;

46 (11) Notwithstanding any other provision in this subsection, the entity conducting
47 the audit shall not use the accounting practice of extrapolation in calculating recoupments
48 or penalties for audits, except as otherwise authorized under subdivision (5) of this
49 subsection.

50 2. Recoupments of any disputed moneys shall only occur after final internal
51 disposition of the audit, including the appeals process set forth in subsection 3 of this
52 section.

53 3. Each entity conducting an audit shall establish an appeals process, lasting no
54 longer than six months, under which a licensed pharmacy may appeal an unfavorable
55 preliminary audit report to the entity. If, following such appeal, the entity finds that an
56 unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss
57 the audit report or such portion without the necessity of any further proceedings.

58 4. Each entity conducting an audit shall provide a copy of the final audit report,
59 after completion of any appeal process, to the plan sponsor.

60 5. This section shall not apply to any audit conducted as a part of an investigation
61 regarding alleged criminal wrongdoing, willful misrepresentation, or abuse.

62 6. This section shall not apply to any audit conducted as part of any inspection or
63 investigation conducted by the board of pharmacy.

64 7. Unless required by federal law, no contract entered into or renewed after the
65 effective date of this section shall contain audit criteria provisions that are more restrictive
66 than the audit criteria provisions contained in this section.

 Section 1. 1. As used in sections 1 to 3, the following words and phrases shall mean:

2 (1) “Generic alternative”, another drug within the same drug class as the originally
3 prescribed medication;

4 (2) “Generic equivalent”, another drug with the same chemical compound as the
5 originally prescribed medication;

6 (3) “Health carrier”, the same meaning as such term is defined in section 376.1350,
7 RSMo;

8 (4) “Pharmacy benefit manager” or “PBM”, a person or entity other than a
9 pharmacy or pharmacist acting as an administrator in connection with pharmacy benefits;

10 (5) “Switch communication”, a communication from a health insurance carrier or
11 PBM to a patient or the patient’s physician that recommends a patient’s medication be
12 switched by the original prescribing health care professional to a different medication than
13 the medication originally prescribed by the prescribing health care professional.

14 **2. (1) Any time a patient's medication is recommended to be switched to a**
15 **medication other than that originally prescribed by the prescribing health care**
16 **professional, a switch communication shall be sent to:**

17 **(a) The patient providing information about why the switch is proposed and the**
18 **patient's rights for refusing the recommended change in treatment; and**

19 **(b) The plan sponsor informing such sponsor of the cost, shown in currency form,**
20 **of the recommended medication and the cost, shown in currency form, of the originally**
21 **prescribed medication.**

22 **(2) A switch communication shall not be required for generic equivalent medication**
23 **switches, unless the cost to the patient or plan sponsor is greater than the medication**
24 **originally prescribed and dispensed.**

25 **(3) A switch communication shall be required for generic alternative medication**
26 **switches.**

27 **3. Such switch communication shall:**

28 **(1) Clearly identify the originally prescribed medication and the medication to**
29 **which it has been proposed that the patient should be switched;**

30 **(2) Explain any financial incentives that may be provided to, or have been offered**
31 **to, the prescribing health care professional by the health carrier or PBM that could result**
32 **in the switch to the different drug. In particular, cash or in-kind compensation payable**
33 **to prescribers or their professional practices for switching patients from their currently**
34 **prescribed medication to a different medication shall be disclosed to the patient as well as**
35 **incentives that may be provided through general health care professional compensation**
36 **programs used by the health carrier or PBM;**

37 **(3) Explain any financial incentive that a health carrier or PBM may have to**
38 **encourage the switch to a different drug;**

39 **(4) Advise the patient of his or her rights to discuss the proposed change in**
40 **treatment before such a switch takes place, including a discussion with the patient's**
41 **prescribing health care professional, the filing of a grievance with the health carrier to**
42 **prevent the switch if such a switch is based on a financial incentive and the filing of a**
43 **grievance with the department of insurance, financial institutions, and professional**
44 **registration; and**

45 **(5) Explain any cost sharing changes for which the patient is responsible.**

46 **4. Switch communications to health care providers shall disclose financial incentives**
47 **or benefits that may be received by the health carrier or PBM.**

48 **5. Switch communications to health care providers shall direct the prescriber to**
49 **advise the patient that is subjected to a switch by the prescriber of any financial incentives**

50 received by the prescriber or other inducements from the health carrier or PBM that may
51 influence the decision to switch.

52 **6. A copy of any switch communication sent to a patient shall also be sent to the**
53 **prescribing health care professional.**

54 **7. Health insurance payers, including employers, shall be notified of medication**
55 **switches among plan participants. Such notification shall include any financial incentive**
56 **the health carrier or PBM may be utilizing to encourage or induce the switch. Information**
57 **contained in the notification shall be in the aggregate and must not contain any personally**
58 **identifiable information.**

59 **8. The department of insurance, financial institutions, and professional registration**
60 **shall create one form for health carriers and pharmacy benefit managers to use in switch**
61 **communications to patients, prescribing health care professionals, and health insurance**
62 **payers including employers.**

63 **9. The department shall promulgate rules governing switch communications.**

64 **10. Such rules shall include, but not be limited to the following:**

65 **(1) Procedures for verifying the accuracy of any switch communications from**
66 **health benefit plans and pharmacy benefit managers to ensure that such switch**
67 **communications are truthful, accurate, and not misleading based on cost to the patient and**
68 **plan sponsor, the product package labeling, medical compendia recognized by the MO**
69 **HealthNet program for the drug utilization review program, and peer-reviewed medical**
70 **literature, with appropriate references provided;**

71 **(2) A requirement that all switch communications bear a prominent legend on the**
72 **first page that states: "This is not a product safety notice. This is a promotional**
73 **announcement from your health care insurer or pharmacy benefit manager about one of**
74 **your current prescribed medications.";**

75 **(3) A requirement that, if the switch communication contains information**
76 **regarding a potential therapeutic substitution, such communication shall explain that**
77 **medications in the same therapeutic class are associated with different risks and benefits**
78 **and may work differently in different patients.**

79 **11. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo,**
80 **that is created under the authority delegated in this section shall become effective only if**
81 **it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if**
82 **applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable**
83 **and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo,**
84 **to review, to delay the effective date, or to disapprove and annul a rule are subsequently**

85 held unconstitutional, then the grant of rulemaking authority and any rule proposed or
86 adopted after August 28, 2008, shall be invalid and void.

2 Section 2. 1. Issuing or delivering or causing to be issued or delivered a switch
communication that has not been approved and is not in compliance with the requirements
3 of section 1 is punishable by a fine not to exceed twenty-five thousand dollars.

4 2. Providing a misrepresentation or false statement in a switch communication
5 under section 1 is punishable by a fine not to exceed twenty-five thousand dollars.

6 3. Any other material violation of section 1 is punishable by a fine not to exceed
7 twenty-five thousand dollars.

2 Section 3. 1. When medications for the treatment of any medical condition are
restricted for use by a health carrier or PBM by a step therapy or fail first protocol, a
3 prescriber may override such restriction if:

4 (1) The preferred treatment by the health carrier or the PBM has been ineffective
5 in the treatment of the covered person's disease or medical condition; or

6 (2) Based on sound clinical evidence and medical and scientific evidence:

7 (a) The preferred treatment is expected to be ineffective based on the known
8 relevant physical or mental characteristics of the covered person and known characteristics
9 of the drug regimen, and is likely to be ineffective or adversely affect the drug's
10 effectiveness or patient compliance; or

11 (b) The preferred treatment has caused or based on sound clinical evidence and
12 medical and scientific evidence is likely to cause an adverse reaction or other harm to the
13 covered person.

14 2. The duration of any step therapy or fail first protocol shall not be longer than
15 a period of fourteen days.

16 3. For medications with no generic equivalent and for which the prescribing
17 physician in their clinical judgment feels that no appropriate therapeutic alternative is
18 available a health carrier or PBM shall provide access to United States Food and Drug
19 Administration (FDA) labeled medications without restriction to treat such medical
20 conditions for which an FDA labeled medication is available.

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